EXHIBIT XIV

EXHIBIT XIV

FIRST QUARTER 1997

ACTIVITY/ DOCUMENT TYPE	SUBJECT
IND Application	Schering IND submission for SCH 58235 for the treatment of primary hypercholesterolemia.
Letter from FDA	Letter from FDA acknowledging receipt of IND for SCH 58235 and assigning IND number: 52791.

SECOND QUARTER 1997

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter from FDA	Letter from FDA outlining deficiencies, placing a clinical hold, and outlining information need to resolve clinical hold deficiencies.
Letter to FDA	Schering response to clinical hold.
Letter from FDA	FDA letter lifting clinical hold if certain changes are made to protocol C960345 and its screening study C96-411.
Letter to FDA	Schering Protocol Amendment: change in protocol.

THIRD QUARTER 1997

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new protocol; new investigator.
Letter from FDA	Note from pharmacology reviewer commenting on human PK data and tissue distribution study.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter from FDA	Clinical pharmacology and biopharmaceutics reviewer comments.
Letter from FDA	Request for additional CMC information believed to be have resulted from incorrect interpretation of capsule strengths versus dose levels in the clinical protocol.
Letter to FDA	Schering Protocol Amendment: new investigators.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: change in protocols and new investigators.

FOURTH QUARTER 1997

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Information Amendment: final study report for I96-088.
Letter to FDA	Schering response to 8/25/1996 fax requesting additional analytical and manufacturing information.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new protocol, new investigator, and amended CMC information.
Letter to FDA	Schering Information Amendment: clinical study report.

FIRST QUARTER 1998

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering proposal for justification of dose level selection for rat oncogenicity study in SCH 58235 for the Carcinogenicity Assessment Committee's review.
Letter to FDA	Schering Protocol Amendment: change in protocols.
Letter from FDA	Pharmacology reviewer's comments.
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Information Amendment: co-investigators added.
Letter to FDA	Protocol Amendment: change in protocols.
Letter to FDA	Fax of Schering Information Amendment sent to Margaret Simoneau.
Letter to FDA	Schering proposal for justification of dose level selection.
Letter to FDA	Schering's response to FDA comments cited in 1/27/1998 fax.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new protocol, new investigator and CMC amendment.

SECOND QUARTER 1998

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Information Amendment: revised FDA Form 1572 for a new investigator.
Letter to FDA	Schering Information Amendment: validation report.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new protocol, new investigator, and revised CMC information.
Letter to FDA	Schering Information Amendment: change in address.
Letter to FDA	Schering Information Amendment: change in protocol.
Letter to FDA	Schering Information Amendment: confirmation letter to FDA regarding telephone conversation between Dr. Lamendola and Dr. Enid Galliers allowing inclusion of Dr. Pickett as individual permitted to review interim analysis without jeopardizing integrity of study.
Letter to FDA	Schering Information Amendment: stability of rabiolabeled SCH 58235 in rats.
Letter to FDA	Schering Protocol Amendment: new protocol and new investigator.

THIRD QUARTER 1998

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Response to 3/24/1998 executive CAC comments (originally dated 2/24/1998).
IND Annual Report	Reported information for the period 05/24/1997 to 05/23/1998 , and included a statement that the investigator's brochure is in the process of being updated and will be submitted as an information amendment.
Letter to FDA	Schering Information Amendment: submission in response to 3/17/2002 request.
Letter to FDA	Schering Information Amendment: subinvestigators added.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter from FDA	Brief summary of executive Carcinogenicity Assessment Committee ("CAC") discussion and recommendations.

FOURTH QUARTER 1998

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Information Amendment: response to 9/30/2002 request for curricula vitae.
Letter to FDA	Schering Information Amendment: clinical study report on food effects on bioavailability in normal male volunteers.
Letter to FDA	Schering Information Amendment: subinvestigator added.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new protocols, updated investigator's brochure, and chemistry/microbiology amendment.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: new investigators.

FIRST QUARTER 1999

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: new investigators.

SECOND QUARTER 1999

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new protocol and new investigator.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Information Amendment: drug metabolism and pharmacokinetic study reports.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new protocol, new investigator, and subinvestigator added to study.
Letter to FDA	Schering Information Amendment: preclinical study report.

THIRD QUARTER 1999

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new protocol and new investigator.
Letter to FDA	Schering request for End of Phase II meeting.
Letter to FDA	Fax of Schering request for End of Phase II meetings for clinical and CMC.
IND Annual Report	Reported information for the period 05/24/1998 to 05/23/1999.
Letter to FDA	Schering Protocol Amendment: new Protocol and new investigator.
Letter to FDA	Schering Briefing book for End of Phase II clinical/preclinical and CMC meetings.
Letter from FDA	FDA fax confirming clinical/preclinical meeting.
Letter to FDA	Schering fax containing corrections on pages 47 and 75 of the tox section of the briefing book.

FOURTH QUARTER 1999

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering submission of additional CMC question for End of Phase II meeting.
Letter to FDA	Schering Protocol Amendment and Information Amendment: two Phase III study protocols, updated FDA Form 1572, and deletion of subinvestigators.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Information Amendment: CMC information to support clinical supplies used in ongoing investigational program.
Letter to FDA	Schering Information Amendment: requested information from completed simvastatin and lovastatin co-administration toxicology studies.
Letter to FDA	Protocol Amendment: New Investigator
Letter from FDA	FDA minutes from End of Phase II CMC meeting with Schering held in 10/20/1999.
Letter from FDA	FDA fax of 10/4/1999 meeting minutes.
Letter to FDA	Schering Information Amendment: summary of 3 month dog mean plasma concentration-time data.
Letter to FDA	Schering Protocol Amendment: two new Phase III protocols for study of SCH 58235 in addition to either lovastatin or simvastatin.
Letter to FDA	Schering Information Amendment: amendment to CMC information providing for alternate placebo capsule.
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Protocol Amendment: new protocols.
Letter to FDA	Schering request for guidance on current dissolution test method for SCH 58235.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new investigator and revised FDA Form 1572.

FIRST QUARTER 2000

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Protocol Amendment: new protocols.
Letter to FDA	Schering Information Amendment: clinical.
Letter to FDA	Schering Information Amendment: final report for studies.
Letter to FDA	Schering Protocol Amendment: new protocol and new investigator.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new investigator and change to investigator's 1573 form.
Letter to FDA	Schering Fax to CSO regarding request for teleconference to discuss SCH 58255 dissolution data and proposed test method for SCH 58235 tablets.
Letter to FDA	Schering Information Amendment: request for teleconference to discuss dissolution data and proposed test method for SCH 58235 tablets.
Letter to FDA	Schering Information Amendment: final reports.
Letter from FDA	FDA confirmation of teleconference to discuss dissolution testing methodology for SCH 58235 and requesting list of sponsor participants.
Letter to FDA	Schering fax to FDA listing Schering participants in teleconference on dissolution testing.
Letter from FDA	FDA minutes of 2/4/2000 teleconference to discuss review of 3 month SIMVA and LOVA coadministration tox reports.
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter from FDA	Confirmed list of FDA participants for 3/14/2000 teleconference to discuss SCH 58235 dissolution testing.
Letter to FDA	Schering minutes of 3/14/2000 FDA teleconference to discuss dissolution testing methodology for SCH 58235 tablets.
Letter from FDA	FDA minutes of 3/14/2000 telecon to discuss dissolution testing methodology for SCH 58235 tablets.
Letter to FDA	Schering Information Amendment: final report.

SECOND QUARTER 2000

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Information Amendment: CMC update.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new protocol and clinical amendment.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter from FDA	Biopharm reviewer request for information on validation of cocktail approach used in I97-137 "SCH 58235: The Effects of SCH 58235 on Drug Metabolizing Enzymes in Healthy Mail Subjects."
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Proposed pediatric study request in pediatric population with heterozygous familial hypercholesterolemia.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: amended protocols.
Letter to FDA	Protocol Amendment: new investigator.
Letter to FDA	Schering Information Amendment: update finished products for revised dissolution method.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: new protocol and new investigator.
Letter to FDA	Schering Protocol Amendment: amended protocols.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new investigator and change in PI.
Letter to FDA	Schering replacement copy of 1/20/2000 amendment (Serial No. 060).
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new investigators and investigators' FDA Form 1572 amended.
Letter to FDA	Schering 15-Day initial safety report.
Letter to FDA	Schering Protocol Amendment: new investigators.

THIRD QUARTER 2000

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Information Amendment: final reports.
Letter to FDA	Schering Protocol Amendment: new investigators.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
IND Annual Report	Reported information for the period 05/24/1999 to 05/23/2000.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering response to medical reviewer's request for clinical information on ezetimibe.
Letter to FDA	Schering Information Amendment: final CSR.
Letter to FDA	Schering Information Amendment: final CSR.
Letter to FDA	Schering Protocol Amendment and Information Amendment: new investigators and clinical amendment.
Letter to FDA	Protocol Amendment: new protocol and new investigator.
Letter to FDA	Protocol Amendment: new protocol.
Letter from FDA	FDA unable to issue a written request for pediatric studies based upon submission of 4/24/2000.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: new protocol and new investigators.
Letter to FDA	Schering request for pre-NDA meeting.

FOURTH QUARTER 2000

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Information Amendment: transfer of obligations.
Letter from FDA	FDA confirmation of pre-NDA meeting schedule.
Letter to FDA	Schering Protocol Amendment: new protocol.
Letter to FDA	Schering pre-NDA CMC meeting request.
Letter to FDA	Schering Information Amendment: final clinical study report.
Letter from FDA	FDA response to pre-NDA CMC meeting request indicating requested meeting will occur on 12/12/2000 and pre-meeting packages should arrive no later than 11/14/2000.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering transfer of the IND to MSP Singapore Co.
Letter to FDA	Schering acceptance of IND by MSP Singapore Co.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment and Information Amendment: new protocol Clinical Update (9/2000) and Investigator's Brochure.
Letter to FDA	Schering Information Amendment: chemistry update.
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Protocol Amendment: new protocols.
Letter to FDA	Schering Information Amendment: final study report regarding multiple dose pharmacodynamic drug interaction between simvastatin and ezetimibe.
Letter to FDA	Schering Information Amendment: Chem/Micro amendment.
Letter to FDA	Schering Information Amendment: investigators' FDA Form 1572 amended.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering correspondence informing FDA that 11/17/2000 submission incorrectly coded as a "Protocol Amendment: New Protocol," but was in fact a Clinical Information Amendment containing final clinical study report.
Letter to FDA	Schering Response to the Biopharm reviewer's 4/12/2000 request for information/data regarding the validation of the cocktail approach used in I97-137.
Letter to FDA	Schering Information Amendment: submission of clinical study report.
Letter to FDA	Schering submission of PK reports in response to 12/1/2000 request of PK review.
Letter to FDA	Schering submission of PK appendix to P01-382 (20 mg LOVA Pharmacokinetic study) per 12/1/2000 request of reviewer, Dr. Wei.
Letter to FDA	Schering Information Amendment: Chem/Micro amendment.
Letter to FDA	Schering Protocol Amendment: new protocol.
Letter to FDA	Schering Protocol Amendment: new protocol.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: new protocol and change in protocol.

FIRST QUARTER 2001

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Protocol Amendment: change in protocol.
Letter to FDA	Schering Information Amendment: final report for 12-month toxicity study in dogs.
Letter to FDA	Schering Information Amendment: Med Watch form for an adverse event of anemia.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Request for pre-NDA meeting.
Letter to FDA	Schering 15-Day initial safety report.
Letter to FDA	Schering Protocol Amendment: new protocol and change in protocol.
Letter from FDA	Assignment of date and time of pre-NDA clinical meeting (4/25/2001 at noon).
Letter to FDA	Schering Request for CMC pre-NDA meeting.
Letter to FDA	Schering Information Amendment: final clinical study report.
Letter to FDA	Schering Information Amendment: Chem/Micro amendment.
Letter from FDA	Confirmation of pre-NDA CMC meeting for ezetimibe.
Letter to FDA	Schering Information Amendment: final report.
Letter to FDA	Schering Protocol Amendment: change in protocol.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Protocol Amendment: new investigators.

SECOND QUARTER 2001

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering briefing book for pre-NDA CMC and clinical meetings.
Letter to FDA	Schering Protocol Amendment: new investigators.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering initial 15-Day safety report.
Letter to FDA	Schering Protocol Amendment: change in protocol.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter from FDA	FDA meeting participant register for the CMC pre-NDA meeting schedule for 4/27/2001.
Letter to FDA	Schering 15-Day initial safety report.
Letter to FDA	Schering minutes of CMC pre-NDA meeting.
Letter to FDA	Schering 15-Day follow-up safety report.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Information Amendment: Chem/Micro amendment.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter from FDA	Final meeting minutes for 04/27/2001 CMC pre-NDA Meeting.
Letter to FDA	Schering 15-Day second follow-up safety report.
Letter to FDA	Schering 15-Day initial safety report.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering minutes of 04/27/2001 CMA pre-NDA meeting.with FDA
Letter to FDA	Schering Letter requesting review of proposed trademark (Zient).
Letter to FDA	Schering Information Amendment: final study report.
Letter to FDA	Schering 15-Day third follow-up IND safety report.
Letter to FDA	Schering statistical data analysis plan.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering letter indicating sponsor would like to discuss in a teleconference the electronic datasets to be submitted in Section 11 of NDA with information regarding the information it plans to submit attached.
Letter to FDA	Information Amendment: investigators' FDA Form 1572 amended.
Letter from FDA	Fax of FDA minutes of 04/25/2001 pre-NDA meeting stating that sponsor agreed to do a BA study; sponsor has different recollection of the meeting.
Letter to FDA	Schering 15-Day initial safety report.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering request for Guidance on API Particle size distribution specification.
Letter to FDA	Schering Information Amendment: update information and packaging site for simvastatin tablets and matching placebo.

THIRD QUARTER 2001

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: change in protocol.
Letter to FDA	Protocol Amendment: new investigator
Letter to FDA	Schering Submission of data analysis plans.
Letter to FDA	Schering fax containing statement of indication, dosage/administration description, how supplied, and mode of action of ezetimibe for use by OPDRA in review of proposed tradename.
Letter to FDA	Schering request for teleconference to discuss Ezetimibe particle size distribution specification.
Letter from FDA	Confirmation of teleconference to discuss API particle size distribution.
Letter to FDA	15-Day Initial Safety Report.
Letter to FDA	Schering Protocol Amendment: new investigator.
IND Annual Report	Information reorted for the period 05/24/2000 to 05/23/2001.
Letter to FDA	Schering Information Amendment: final study report.
Letter to FDA	Schering Clarification of FDA minutes of 4/27/2001 pre-NDA CMC meeting with Merck and Schering.
Letter to FDA	Schering 15-Day first follow-up safety report.
Letter to FDA	Schering Information Amendment: transfer of obligations.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Information Amendment: submission of updated version of Investigator's Brochure.
Letter to FDA	Schering 15-Day second follow-up safety report.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering submission of example of a derived dataset, data dictionary and word listing of all datasets planned for P00-474, 08/07/2001.
Letter to FDA	Schering Information Amendment: final reports for studies characterizing the multiple-dose interaction between ezetimibe and fluvastatin or pravastatin in healthy volunteers.
Letter to FDA	Schering Information Amendment: summary of results and literature review.
Letter to FDA	Schering minutes of 7/31/2001 teleconference to discuss API particular size distribution specification.
Letter to FDA	Schering Protocol Amendment: change in protocol.
Letter to FDA	Schering Information Amendment: final reports for studies characterizing multiple-dose interaction between ezetimibe and atorvastatin or lovsatatin in healthy volunteers.
Letter to FDA	Schering Clarification of minutes of 4/25 pre-NDA meeting and request to amend minutes.
Letter from FDA	FDA minutes of 7/31/2001 teleconference to discuss Ezetimibe particle size distribution specification.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Information Amendment: investigators' FDA Form 1572 amended.
Letter to FDA	Schering request for guidance on physician samples and commercial bottles of 90 tablets.
Letter from FDA	Fax from the statistical reviewer containing an example of additional data he may request during the NDA review.
Letter to FDA	Schering Information Amendment: final report.
Letter to FDA	Schering Information Amendment: statistical data analysis plan.
Letter to FDA	Schering 15-Day initial safety report.
Letter to FDA	Schering Information Amendment: clinical monotherapy study report for two, Phase III ezetimibe monotherapy studies.
Letter to FDA	Schering 15-Day first follow-up safety report.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering submission of proposed pediatric exclusivity request.

FOURTH QUARTER 2001

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering response to FDA request for additional documentation concerning clarification of FDA minutes of 4/27/2001 pre-NDA CMC meeting with Merck and Schering.
Letter to FDA	Schering Minutes of 9/6/2001 teleconference to discuss ISS and ISE.
Letter to FDA	Schering fax of FDA minutes of 9/6/2001 teleconference to discuss the ISS and ISE.
Letter from FDA	Fax of FDA minutes of 9/6/2001 teleconference to discuss the ISS and ISE.
Letter from FDA	Fax assigning user fee number and NDA number: NDA # 21-445 and user fee # 4220.
Letter to FDA	Schering request for ISS reviewer to review planned analyses for evaluating certain types of adverse events.
Letter to FDA	Schering Information Amendment: final clinical study report.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering Response to 04/25/2001 FDA request for information on summary of results from study of ezetimibe in patients with homozygous sitosterolemia.
Letter from FDA	FDA final minutes of 10/12/2001 teleconference regarding anhydrous verses hydrous forms of the drug substance.
Letter from FDA	FDA will not issue a written request for pediatric exclusivity (response to 9/26/2001 submission).
Letter from FDA	Final minutes of 10/12/2001 teleconference.
Letter to FDA	Schering 15-Day fourth follow-up safety report.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter from FDA	Hard copy of letter denying pediatric study request (exclusivity) previously received by fax on 11/1/2001
Letter to FDA	Protocol Amendment: Clinical.
Letter to FDA	Schering Information Amendment: investigators' FDA Form 1572 amended.
Letter to FDA	Schering Letter withdrawing Zient as candidate for tradename and requesting review of Zetia.
Letter from FDA	Addendum to FDA meeting minutes of pre-NDA CMC meeting.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering response to request made by clinical team during 09/06/2001 teleconference for an outline of ISE and ISS.
Letter to FDA	Schering Protocol Amendment: new protocol.
Letter to FDA	Schering follow-up to 11/19/2007 submission of proposed trademark correcting indication statement for sitosterolemia.
Letter to FDA	Schering proposal that for future clinical trials the parent company (i.e., Merck or Schering) which assumes primary responsibility for the trail make the required submission to IND.
Letter to FDA	Schering Information Amendment: chemistry amendment.
Letter to FDA	Schering statistical data analysis plan for Phase III study.
Letter to FDA	Schering submission of dissolution profiles for hydrous and anhydrous forms utilizing two dissolution media.
Letter to FDA	Schering Protocol Amendment: change in protocol.
Letter to FDA	Schering Protocol Amendment: new investigators.
Letter to FDA	Schering submission of proposed table of contents for 4-month safety update.

FIRST QUARTER 2002

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering draft protocol regarding "Assessment of the Effect of Micronized Active Pharmaceutical Ingredient (API) Particule Size Distribution (PSD) on the Bioavailability of Ezetimibe 10 mg Tablets" referencing 7/31/2001 teleconference.
Letter to FDA	Schering Protocol Amendment: new investigators.
Fax from FDA	Statistical reviewer's response to statistical data analysis plan (submitted 12/14/2001) for Phase III study.
Letter to FDA	Merck Protocol Amendment: new investigators.
Letter to FDA	Merck Protocol Amendment: new investigators.
Letter to FDA	Merck Protocol Amendment: new protocol.
Letter to FDA	Merck Protocol Amendment: new protocol and new investigator.
Letter to FDA	Schering letter regarding transfer of sponsor obligations.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Merck Information Amendment: amendment to drug product manufacturing sites and active comparators.
Letter to FDA	Schering 15-Day fifth follow-up safety report.
Letter to FDA	Schering Information Amendment and Protocol Amendment: investigators' FDA Form 1572 amended and new investigators.
Letter to FDA	Merck general correspondence and request for meeting (bioequivalence).
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter From FDA	Comments from biopharmaceutics reviewer to amendment dated 11/21/2001.
Letter from FDA	Comments from biopharmaceutics reviewer to amendment dated 1/10/2002.
Letter from FDA	FDA letter instruction that pre-meeting package of no more than 1" to 1.5" must be received by 3/8/2002.
Letter to FDA	Merck Protocol Amendment: new investigators.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Merck general correspondence proposing 4/8/2002 meeting, a list of MSP joint venture participants, brief report on combination formulation, summary of pilot bioequivalence study, and plans/rationale for definitive bioequivalence study.
Letter from FDA	Teleconference scheduled for 3/14/2002.
Letter to FDA	Merck Protocol Amendment: new protocol.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter from FDA	Response to amendment dated 12/17/2001 indicating that FDA concurs that BE study not required for hydrous v. anhydrous forms of ezetimibe tablets.
Letter to FDA	Merck Protocol Amendment: new investigator.
Letter to FDA	Schering response containing sample graphs and tables using P00474 to address questions 1, 2, & 3.
Letter to FDA	Schering response to FDA comments of 3/1/2002 regarding draft bioequivalence protocol submitted on 1/10/2002 and SP's

ACTIVITY/ DOCUMENT TYPE	SUBJECT
	minutes of 3/14/2002 teleconference.
Letter to FDA	Merck fax of response to FDA comments regarding draft bioequivalence protocol and minutes of teleconference of 3/14/2002.

SECOND QUARTER 2002

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Merck Protocol Amendment: change in protocol 027-01.
Letter to FDA	Merck Information Amendment: CMC amendment.
Letter to FDA	Merck Information Amendment: CMC amendment.
Letter to FDA	15-Day second follow-up safety report.
Letter to FDA	Schering response to 4/12/2002 fax providing FDA responses and noting comments remaining for discussion at 4/16/2002 meeting.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Merck Protocol Amendment: new investigator.
Letter to FDA	Merck Information Amendment: CMC amendment.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Schering response to 02/27/2002 fax recommending drug interaction study indicating will conduct an *in vitro* assay using human liver mircosomes pooled from multiple organ donor to assess ezetimbe inhibition of CYP2C8.
Letter to FDA	Merck Information Amendment: contract research obligation transfer of sponsor obligations.
Letter to FDA	Schering 15 day third follow-up safety report.
Letter to FDA	Schering authorization for FDA to cross-reference IND 52,791 and NDA 21-445 to support use of ezetimibe in an IND submitted by Victor Novarro, M.D.
Letter from FDA	Clinical Trials Data Bank.
Letter from FDA	FDA Minutes for 3/14/2002 teleconference.
Letter to FDA	Merck Information Amendment: clinical data analysis plan.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new protocol.
Letter to FDA	Merck Information Amendment: CMC amendment.
Letter to FDA	Schering General Correspondence regarding discontinuation of site 164 from study due to issues of non-compliance with good clinical practices.
Letter to FDA	Merck request for authorization to export quantities of the investigational drug to be studied under IND 52,791 for treatment of hypercholesterolemia.
Letter to FDA	Schering Information Amendment: CMC amendment.
Letter to FDA	Merck General Correspondence and request for meeting/teleconference regarding clinical equivalence.
Letter to FDA	Merck Information Amendment: CMC amendment.
Letter to FDA	Schering Information Amendment and Protocol Amendment: new investigators and amendment to active comparators section.
Letter to FDA	Schering 15-Day fourth follow-up safety report.
Letter from FDA	FDA confirmation of meeting requested on 5/21/2002 for 7/31/2002.
Letter to FDA	Merck Protocol Amendment: new protocol.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Schering Protocol Amendment: new protocol -- study to determine the bioequivalence of two ezetimibe 10 mg batches with reference made to 7/31/2002 discussion in which Division stated that sponsor should demonstrate bioequivalence of dosage forms with release specification at two extremes of particle size.
Letter to FDA	Schering response to comments of 2/27/2002, 3/14/2002 teleconference, and 4/18/2002 submission -- report from *in vitro* assay using human liver micorsomes pooled from multiple organ donors to assess ezetimibe inhibition of CYP2C8.
Letter from FDA	FDA response to 4/18/2002 amendment accepting the use of human liver microsomes to assess ezetimibe inhibition of CYP2C8.
Letter to FDA	Schering 15-Day initial safety report.
Letter to FDA	Merck response to FDA request for information regarding the differences between the referenced draft combination tablet factorial protocol and the completed Schering P00680 ezetimibe and simvastatin co-administration factorial protocol with parallel

ACTIVITY/ DOCUMENT TYPE	SUBJECT
	design that was submitted in NDA 21-445.

THIRD QUARTER 2002

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter from FDA	Clinical Trials Data Bank.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Merck Information Amendment: CMC amendment.
Letter to FDA	Schering response to 1/24/2002 letter from statistical reviewer containing comments on the statistical data analysis submitted on 12/14/2001.
Letter to FDA	Schering Information Amendment: clinical study reports.
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter from FDA	Comments and request for additional information regarding amendment dated 6/17/2002 indicating that these are not clinical hold issues but that a response is requested.
IND Annual Report	Information reported for the period 05/24/2001 to 05/23/2002.
Letter from FDA	Comments from statistical reviewer regarding amendment dated 5/10/2002.
Letter to FDA	Schering Information Amendment and Protocol Amendment: new investigator and clinical amendment.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Merck response to FDA comments on data analysis plan provided in 7/24/2002 fax from statistical reviewer.
Letter from FDA	Clinical Trails Data Bank.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Merck Protocol Amendment: new investigators.
Letter to FDA	Merck Protocol Amendment: new investigators.
Letter to FDA	Schering Information Amendment: CMC amendment.
Letter to FDA	Schering Protocol Amendment: change in protocol.

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Merck response to FDA 7/19/2002 comments and request for additional information.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Merck Protocol Amendment: new investigators.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Merck Protocol Amendment: new investigators.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Schering 15-Day first follow-up safety report.
Letter to FDA	Merck Protocol Amendment: change in protocol.
Letter to FDA	Merck letter regarding import for export.
Letter to FDA	Merck 15-Day second follow-up safety report.
Letter to FDA	Merck Protocol Amendment: new investigator.
Letter to FDA	Schering Protocol Amendment: new investigator.

FOURTH QUARTER 2002

ACTIVITY/ DOCUMENT TYPE	SUBJECT
Letter to FDA	Schering Protocol Amendment: new investigator.
Letter to FDA	Schering Information Amendment and Protocol Amendment: new investigators.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Merck Information Amendment: clinical amendment.
Letter to FDA	Merck Protocol Amendment: new investigator.